

Notice of Allowability

Application No.

09/680,121

Examiner

Gary B. Nickol Ph.D.

Applicant(s)

FRENCH ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06-14-04.
2. ☒ The allowed claim(s) is/are 63-65.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

GARY NICKOL
PRIMARY EXAMINER

Gary B. Nickol

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit: 1642

Art Unit: 1642

Re: French *et al.*

Date of priority: 03/07/1997

The Election filed March 20, 2004 in response to the Office Action of 02-24-04 is acknowledged and has been entered.

Applicant's election with traverse of Group IV, claim 63 is acknowledged. The traversal is on the ground(s) that the requirement that applicant file 20 more patent applications would impose a staggering financial burden on the applicant. Applicants argue that it would also overwhelm an already struggling biotech examination operation within the USPTO. This is not found persuasive.

The Office does not set any particular limits on the total number of inventions per application. Each application must be examined on its own merits, and MPEP 802.01 provides that restriction is proper between inventions that are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the action mailed 02-24-04. However, upon review and reconsideration, **Group IV and Group VI are rejoined**. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Mueth on June 14, 2004.

The application has been amended as follows:

58-62 (Cancelled)

63. **(Amended)** A method for detecting a polypeptide comprising of SEQ ID NO:2 in a sample, comprising the steps of:

- (a) contacting the sample with an antibody that specifically binds to ~~the~~ said polypeptide and
- (b) detecting specific binding between the antibody and the ~~said~~ polypeptide, whereby specific binding provides a detection of the ~~said~~ polypeptide in the sample.

64. **(Amended)** A method for use in the diagnosis of prostate cancer in a subject comprising the steps of:

- (a) detecting a diagnostic amount of ~~mRNA of SEQ ID NO:1 or the~~ polypeptide of SEQ ID NO:2 in a sample from the subject wherein said polypeptide is detected by contacting the sample with an antibody that specifically binds to the polypeptide of SEQ ID NO:2; and
- (b) comparing the diagnostic amount with a normal range of ~~SEQ ID NO:1 mRNA or~~ SEQ ID NO:2 polypeptide in a non-cancerous control sample, whereby a diagnostic amount above the normal range provides a positive indication in the diagnosis of prostate cancer.

65. **(Amended)** The method of claim ~~68~~ 64 wherein the sample is blood, urine, lymph node tissue or prostate tissue.

66-76. (Cancelled).

The following is an examiner's statement of reasons for allowance: Claims drawn to the isolated polypeptide are free of the art. Further, the specification supports (page 35, lines 15-33) an enabling disclosure for discriminating between non-cancerous and cancerous prostate tissue wherein detection of the claimed polypeptide indicates cancerous prostate tissue.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

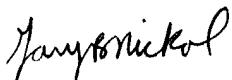
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

June 15, 2004



**GARY NICKOL
PRIMARY EXAMINER**